

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF TENNESSEE  
NASHVILLE DIVISION

UNITED STATES OF AMERICA <i>ex rel.</i>	)	
JEFFREY H. LIEBMAN and DAVID M.	)	
STERN, M.D.,	)	Case No.: 3:17-cv-00902
	)	
Plaintiff-Relators,	)	JUDGE CAMPBELL
	)	MAGISTRATE JUDGE HOLMES
v.	)	
	)	
METHODIST LE BONHEUR HEALTHCARE	)	
and METHODIST HEALTHCARE-MEMPHIS	)	
HOSPITALS,	)	
	)	
Defendants.	)	

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**UNITED STATES' MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO  
EXCLUDE METHODIST FROM INTRODUCING EVIDENCE OF SAFE HARBORS**

Pursuant to Rules 402 and 403 of the Federal Rules of Evidence, the United States of America ("United States") submits this memorandum of law in support of its motion *in limine* to exclude Defendants Methodist Le Bonheur Healthcare and Methodist Healthcare-Memphis Hospitals ("Methodist") from presenting evidence regarding the existence of exceptions to the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"), known as safe harbors, which are found at 42 CFR § 1001.952, and specifically evidence identifying the elements of the personal services and management contracts ("personal services") safe harbor in effect during the relevant time period, together with any amendments thereto, as well as evidence that Methodist should not be liable for any AKS violation because it has satisfied any individual element of the personal services safe harbor, and evidence relating to any guidance, advisory opinions or proposed rule changes

concerning the personal services safe harbor, as Methodist has not asserted any safe harbor to the AKS as an affirmative defense in this action.

Because Methodist is not asserting that the conduct the United States has alleged falls under any safe harbor to the AKS, the evidence is not relevant to any defense. If Methodist is permitted to introduce evidence that the agreements at issue satisfy individual elements of the personal services safe harbor, whether the version in effect during the relevant time period or any amendments, it would result in a backdoor assertion of an unasserted affirmative defense. Methodist also should not be permitted to introduce any guidance or statements relating to the personal services safe harbor made after the time period of the conduct at issue. In sum, introduction of evidence relating to the safe harbor should be excluded because it is irrelevant, and otherwise would be prejudicial to the United States and serve to confuse and mislead the jury.

### BACKGROUND

#### A. Summary of the United States' AKS Allegations

In this action, the United States has alleged that Methodist violated the AKS by paying unlawful remuneration to The West Clinic, P.C. (“West”) in exchange for patient referrals. (ECF No. 235 at ¶ 353.) The payments were made through the various transaction documents entered into between Methodist and West that were in effect from January 1, 2012 through December 31, 2018, including an Asset Purchase Agreement (“APA”), a Professional Services Agreement (“PSA”), a Leased Employee and Administrative Services Agreement (“LEA”) and a Management Services/Performance Improvement Agreement (“MSA”). (*Id.* at ¶¶ 3, 10.) The relationship between Methodist and West terminated on February 23, 2019. (*Id.* at ¶ 348.)

The United States does not allege that all the payments were fraudulent or that West did not perform any services or satisfy any of the obligations under the various contracts. Rather, the

United States alleges that agreements with West were a vehicle to disguise the kickbacks. For example, under the APA, Methodist paid West for assets that Methodist did not acquire. Under the PSA, Methodist paid West for certain professional services performed by nurse practitioners who were leased to Methodist under the LEA. Kickbacks also came through payments to West under the MSA, even though West did not perform all the base management services required by the MSA, in all the locations. Methodist even agreed to and did increase the amount it paid to West under the MSA two years into the contractual relationship, knowing that West had not performed all the base management services under the MSA. Methodist also paid West millions of dollars under the MSA knowing that Erich Mounce, West's Chief Executive Officer who was leased full-time to Methodist under the LEA, also was the Administrator tasked with oversight for the MSA. Further, kickbacks were paid because, under the LEA, Methodist paid the entire salary for West employees and an independent contractor who were leased full-time to Methodist and still performed work for West, including Mr. Mounce and Ronald Davis, West's Chief Financial Officer. In addition, Methodist paid kickbacks to West by allowing West to continue operating its business out of a location Methodist acquired under the APA, and then later out of a location that Methodist owned without requiring West to pay any rent. *See, e.g.*, ECF No. 296-1 at 4-9 (further detailing the alleged unlawful remuneration). The United States contends that because Methodist violated the AKS, it submitted false claims to Medicare certifying its compliance with the AKS, which constitute violations of the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA").

B. The Safe Harbors to The AKS

The AKS and its corresponding regulations exempt certain payments, commonly referred to as the "safe harbor" provisions. One such exception is the personal services safe harbor. 42 CFR § 1001.952(d).

During the relevant time period, the personal services safe harbor stated:

“remuneration” does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following seven standards are met—

- (1) The agency agreement is set out in writing and signed by the parties.
- (2) The agency agreement covers all of the services the agent provides to the principal for the term of the agreement and specifies the services to be provided by the agent.
- (3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
- (4) The term of the agreement is for not less than one year.
- (5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs.
- (6) The services performed under the agreement do not involve the counselling or promotion of a business arrangement or other activity that violates any State or Federal law.
- (7) The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

42 CFR § 1001.952(d) (2007).

The personal services safe harbor has been amended since the time Methodist entered into the relationship with West. In October 2019, proposed amendments, together with comments, were published in the Federal Register. 84 Fed. Reg. 201, 55694 (Oct. 17, 2019.) In December

2020, a notice of final rulemaking was published in the Federal Register, again with comments. 85 Fed. Reg. 232, 77684 (Dec. 2, 2020).

Of note is that the title of the personal services safe harbor, changed from “personal services and management contracts” when the parties entered into the agreements to “personal services and management contracts and outcomes-based arrangements,” which provides an exception for certain conduct intended to provide a benefit to patients if all of the elements of the safe harbor are satisfied. *Compare* 42 CFR § 1001.952(d) (2007) *with* 42 CFR § 1001.952(d) (2021). Once the proposed amendments became final, the new safe harbor language was made effective. The amendments do not state that they are to be applied retroactively. Therefore, the amendments do not cover the conduct at issue in this litigation, all of which occurred prior to the amendments.

Prior to the Court granting approval for the United States to intervene in this litigation, Methodist had not responded to any complaint that Relators had filed in this action. Methodist also refused to confirm to Relators or to the United States whether it would assert any safe harbor to the AKS as an affirmative defense, including the personal services safe harbor.

On April 11, 2022, the United States filed its Complaint in Intervention. (ECF No. 235.) Not knowing whether Methodist intended to assert any safe harbor as an affirmative defense, the United States included allegations that identified the agreements at issue did not satisfy certain elements of the personal services safe harbor, including that aggregate compensation was not set in advance and that the payment could not take into the volume or value of referrals. The United States further alleged that although safe harbors to the AKS exist, none are applicable here. (*See* ECF No. 302 at 3.)

On May 17, 2022, Methodist filed its Answer. (ECF No. 242.) It did not assert that any safe harbors to the AKS as an affirmative defense in this action. Methodist admits that it is not asserting a safe harbor as a defense in this action. (Exhibit A.)

Accordingly, the United States does not intend to introduce evidence of the existence of the safe harbors or any element of the personal services safe harbor.

C. Methodist Sought Information from the United States Relating to Safe Harbors

Even though Methodist has confirmed it is not asserting a safe harbor as an affirmative defense (Exhibit A), Methodist has served document requests, interrogatories, and requests for admission (RFAs) that sought information from the United States, both directly and indirectly, as to facts relevant to the safe harbors, including notions of “fair market value” and in particular the personal services safe harbor. (ECF No. 296-2 at Doc. Reqs. No. 16, 20-25, 33; ECF No. 296-1 at Interrogatory Nos. 10-12, 15; ECF No. 271-6 at RFAs 3-5, 7-8.) Although the United States objected to providing documents and information relating to the safe harbor, and repeatedly informed Methodist that the safe harbor was not relevant, Methodist continued to pursue responses.

Because there were no documents or information relating to much of the contested discovery, the United States ultimately responded to the document requests and the interrogatories, without waiving its objections. However, the United States refused to respond to Methodist’s RFAs 3-5, 7 and 8, as requests for admission are not a discovery tool but intended to narrow issues for trial. *See, e.g., Misco, Inc. v. U.S. Steel Corp.*, 784 F.2d 198, 205 (6th Cir. 1986), *Tolson v. Washburn*, Case No. 3:19-00175, 2022 WL 1479945, at \*4 (M.D. Tenn. May 10, 2022) (Newbern, J.). The United States’ responses to the RFAs now are the subject of pending motions. (ECF Nos. 301-303.)

RFAs 7 and 8 quote directly from comments related to proposed rulemaking in connection with the amendments to the personal services safe harbor. RFA No. 7 states: “Admit that CMS and HHS have proposed rules seeking to promote *flexibility* and *innovations* in the delivery or [sic] more efficient and *better coordinated care*.” (ECF No. 271-6 at 6-7) (emphasis added). This language paraphrases statements made in the Federal Register in December 2020 in connection with the proposed amendments to the personal services safe harbor: “In this final rule, we sought to strike the right balance between flexibility for beneficial innovation and better coordinated patient care with necessary safeguards to protect patients and Federal health care programs.” 85 Fed. Reg. 232, 77685 (Dec. 2, 2020).

RFA 8 states: “Admit that CMS and HHS have acknowledged a ‘compelling concern’ that uncertainty and regulatory barriers could ‘prevent the best and most efficacious innovations from emerging and being tested in the marketplace.’” (*Id.*) Specifically, in RFA 8, Methodist has quoted statements in the Federal Register in October 2019 relating to a proposed amendments to the personal services safe harbor:

There is a compelling concern that uncertainty and regulatory barriers—real or perceived—could *prevent the best and most efficacious innovations from emerging and being tested in the marketplace*. Our goal is to craft safe harbors that, *if finalized*, would protect arrangements that promote value, while also protecting against fraud, abuse and associated harms. Over time, we expect that best practices in care coordination and value-based payment will emerge.

84 Fed. Reg. 201, 55699 (Oct. 17, 2019) (emphasis added).

RFA 4 expressly references the term “safe harbor” and contains other elements that implicate concepts found in the personal services safe harbor, such as “fair market value” as noted above. Similarly, RFAs 3 and 5 also implicate the outcomes-based arrangements that are found in

the amendments to the personal services safe harbor and guidance published in connection therewith.

D. The Safe Harbor-Related Evidence Methodist Intends to Offer

Methodist has advised the Court that RFA 4 seeks relevant information because to defend unspecified allegations “Methodist intends to show that the government has never issued any rules, regulations, guidance, official publications, provider education material, or reports forbidding the aspects of the West Cancer Center affiliation that the United States contends were unlawful.” (ECF No. 302 at 2.) Methodist has indicated that it intends to use the responses to the RFAs 7 and 8, which directly quote comments relating to the personal services safe harbor, to “show that, contrary to the government’s allegations, the intent of the parties’ affiliation was to promote the delivery of more efficient and better coordinated care through various innovations achieved through the parties’ agreements.” (ECF No. 303 at 1.)

Similarly, Methodist has informed the Court that it intends to introduce the responses to the RFAs 3 and 5, as “part of its defense” to show “that, contrary to the government’s allegations, the affiliation was designed to—and did—improve the overall quality, efficiency, and effectiveness of the cancer care delivered at Methodist, as was the parties’ express intent in creating and co-managing the cancer center.” (ECF No. 301 at 1-2.) Methodist further states: “‘Along with this evidence of improved care, Methodist also will show that the government has not identified any adverse impact on patient outcomes resulting either from the ‘structure of the Affiliation Agreements,’ (RFA No. 3), or ‘the co-management of any Methodist patients’ care by the West Cancer Center,’ (RFA No. 5).” *Id.* at 2.

Incredibly, despite directly quoting, paraphrasing, and mentioning “safe harbor” in its RFAs, Methodist contends that “RFA 4, 7, and 8 have nothing to do with safe harbors.” (Exhibit



A.) Because Methodist is seeking rulings that RFAs 4, 7 and 8 (as well as RFAs 3 and 5), which relate to the safe harbor, should be deemed admitted, and it has identified how it intends to use such evidence, likely on summary judgment, in addition to trial, the United States now files this motion *in limine*.<sup>1</sup>

### ARGUMENT

The Federal Rules of Evidence define “relevant evidence” as “evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence.” FED. R. EVID. 401. “Evidence that is not relevant is not admissible.” FED. R. EVID. 402. Courts also may exclude otherwise “relevant evidence if its probative value is substantially outweighed by a danger of” ... “unfair prejudice, confusing the issues, [or] misleading the jury.” FED. R. EVID. 403.

#### I. EVIDENCE OF AN UNASSERTED AFFIRMATIVE DEFENSE IS INADMISSIBLE

The United States does not intend to introduce any evidence of the existence of safe harbors to the AKS in this action or any of the specific elements of the personal services safe harbor. Methodist did not assert any safe harbor as an affirmative defense in its Answer, and it acknowledges that it is not asserting any safe harbor as a defense in this action. (Exhibit A.)

Although the Sixth Circuit has not squarely addressed the issue, other circuit courts have found that the safe harbor provisions of the Anti-Kickback Statute qualify as an affirmative

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<sup>1</sup> Requests to admit are used to narrow the disputed issues at trial and not a discovery device. *Misco, Inc. v. U.S. Steel Corp.*, 784 F.2d 198, 205 (6th Cir. 1986), *Tolson v. Washburn*, Case No. 3:19-00175, 2022 WL 1479945, at \*4 (M.D. Tenn. May 10, 2022) (Newbern, J.). As fact discovery has concluded, and the Court has made clear that it will not move the November 2023 trial date, this motion is not premature. Not only will an evidentiary ruling on this discrete issue narrow the disputed issues for trial, it will inform the parties on matters concerning the proper subjects of expert testimony and as to issues ripe for summary judgment, thereby reducing, if not avoiding, further motion practice before the Court.

defense. *See, e.g., U.S. v. Vernon*, 723 F.3d 1234, 1271 (11th Cir. 2013) (describing “bona fide” employee provision as an affirmative defense); *U.S. v. Turner*, 561 Fed. Appx. 312, (5th Cir. 2014) (“The safe harbor provision [of the Anti-Kickback Statute] is an affirmative defense which the defendant must prove...”); *U.S. v. Norton*, 17 Fed. Appx. 98, 102 (4th Cir. 2001) (same). Further, courts within the Sixth Circuit have generally treated statutory safe harbor provisions as affirmative defenses. *See Pfeil v. State St. Bank & Tr. Co.*, 671 F.3d 585, 599 (6th Cir. 2012), *abrogated by Fifth Third Bancorp v. Dudenhoeffer*, 134 S. Ct. 2459, 189 L. Ed. 2d 457 (2014) (ERISA section 404(c) safe harbor is an affirmative defense); *U.S. v. Trumbo*, Case No. 18-20403, 2019 WL 3289848 (E.D. Mich. Jul. 22, 2019) (finding AKS safe harbor an affirmative defense); *U.S. ex rel. Gale v. Omnicare, Inc.*, No. 1:10-CV-127, 2013 WL 3822152, at \*3 (N.D. Ohio July 23, 2013) (addressing motion to strike affirmative defenses of AKS safe harbor provisions). Because Methodist has not asserted that any safe harbor is an affirmative defense to this action, evidence relating to safe harbors has no relevance in this action and should be excluded under Rule 402.

Indeed, this precise issue was addressed by the court in *Trumbo*. In that case, the court found that where a defendant did not assert a safe harbor to the AKS as an affirmative defense, it was irrelevant and could not be referenced. *Trumbo*, 2019 WL 3289848, at \*2. Here, as in *Trumbo*, Methodist should not be allowed to introduce any evidence that safe harbors to the AKS exist or that it complied with any specific elements of the personal services safe harbor. Methodist also should not be able to reference any amendments to the safe harbor, which occurred after the conduct at issue, or any guidance, advisory opinions, or comments relating to the safe harbors.

II. EVIDENCE OF SAFE HARBORS IS CONFUSING AND WILL MISLEAD THE JURY

To include evidence that the AKS has certain safe harbors, some of which were amended after the conduct at issue, also would be confusing and misleading to the jury. If Methodist is allowed to present evidence relating to the safe harbors, including the elements of the personal services safe harbor, it will not be more prejudicial than probative of any issue in this case. For example, if jury hears about the existence and purposes of safe harbors, it likely would need to be instructed to disregard that evidence as Methodist has not invoked a safe harbor. It also would be confusing for a jury to delineate between the elements of the personal services safe harbor that may have been satisfied and those that have not, understand that amendments to the safe harbor were made after the conduct at issue and do not bear on whether Methodist violated the AKS, understand that the United States does not need to show that Methodist failed to satisfy the safe harbor to prove an AKS violation, and that a safe harbor is not a defense that Methodist is asserting in this action.

For similar reasons, the court in *Trumbo* also found that evidence of an AKS safe harbor that was not asserted would be confusing to the jury and excluded such evidence on that basis as well. *Trumbo*, 2019 WL 3289848, at \*2. Thus, evidence relating to safe harbors, including any elements of the personal services safe harbor, also should not be admitted under Rule 403.

## CONCLUSION

For the foregoing reasons, the Court should exclude evidence relating to the existence of safe harbors to the AKS, including any individual elements of the safe harbors, and any rules, regulations, amendments, proposed amendments, guidance, advisory opinions, or publications relating to the safe harbors.

Dated: January 13, 2023

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### CERTIFICATE OF SERVICE

I hereby certify that on January 13, 2023, a true and correct copy of the foregoing was served via email to the following:

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